

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DNB

Display Date 12-20-02

Publication Date 12-23-02

Certifier R. LEDESMA

Cardiovascular and Renal Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Cardiovascular and Renal Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on January 6, 2003, from 8:30 a.m. to 5 p.m.; and on January 7, 2003, from 8 a.m. to 4:30 p.m.

Location: Holiday Inn, Kennedy Ballroom, 8777 Georgia Ave., Silver Spring, MD.

Contact Person: Jayne E. Peterson, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, 5630 Fishers Lane, rm. 1093) Rockville, MD 20857, 301-827-7001, petersonj@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12533. Please call the Information Line for up-to-date information on this meeting. When available, background materials for this meeting will be posted 1-business day prior to the meeting on the FDA Web site at www.fda.gov/ohrms/

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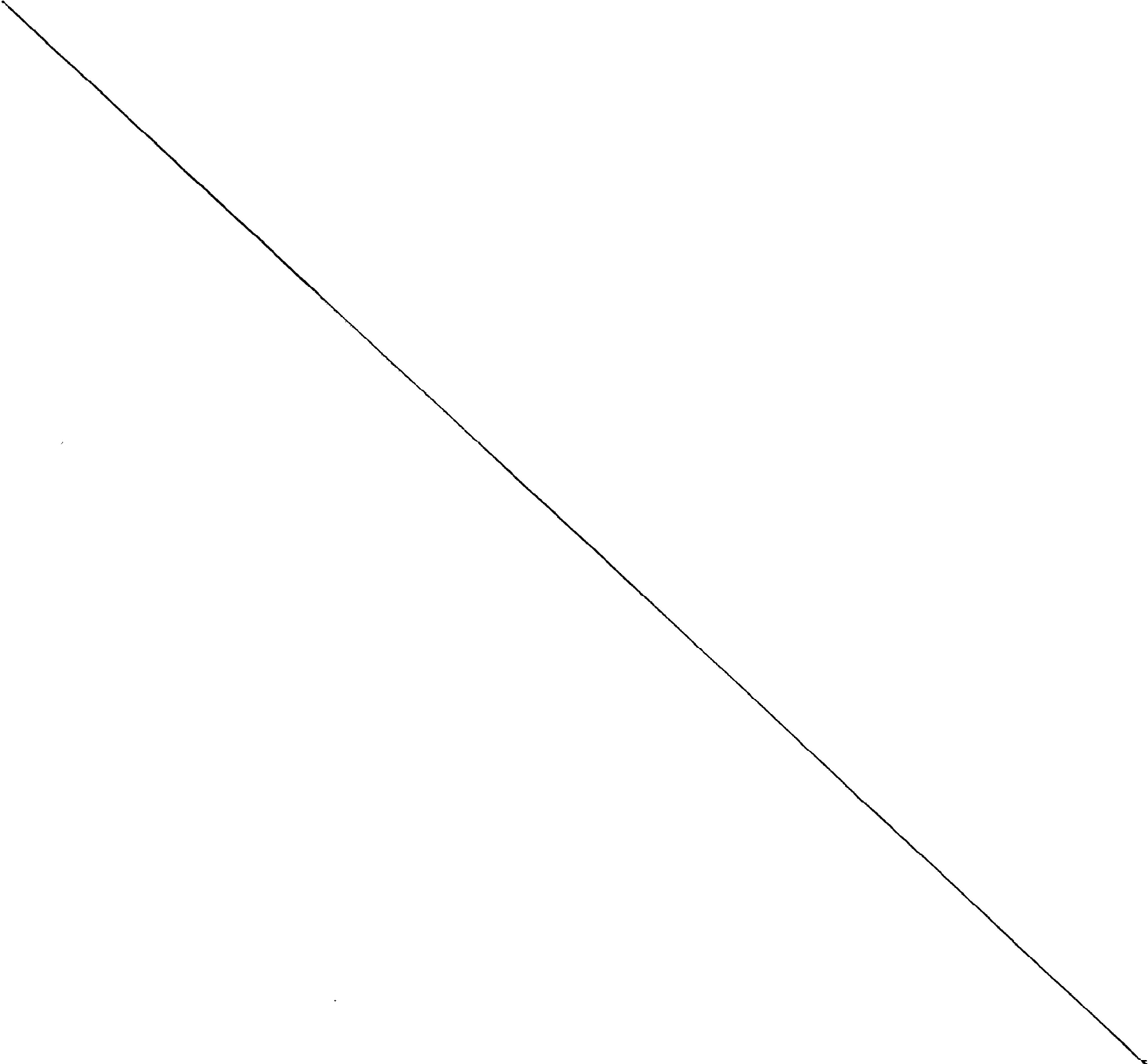
dockets/ac/acmenu.htm. (Click on the year 2003 and scroll down to Cardiovascular and Renal Drugs Advisory Committee.)

Agenda: On January 6, 2003, beginning at 8:30 a.m., the committee will discuss supplemental new drug application (SNDA) 20–386/S–032, COZAAR (losartan potassium) Tablets, Merck and Co., for the proposed indication of reduction in the risk of cardiovascular morbidity and mortality as measured by the combined incidence of cardiovascular death, stroke, and myocardial infarction in hypertensive patients with left ventricular hypertrophy. On January 7, 2003, beginning at 8 a.m., the committee will discuss SNDA 20–297/S–009, COREG (carvedilol), GlaxoSmithKline, for the proposed indication to reduce mortality and the risk of infarction in clinically stable patients who have survived the acute phase of a myocardial infarction and have a left ventricular ejection fraction ≤ 40 percent.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by December 23, 2002. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on January 6 and 7, 2003. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before December 23, 2002, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

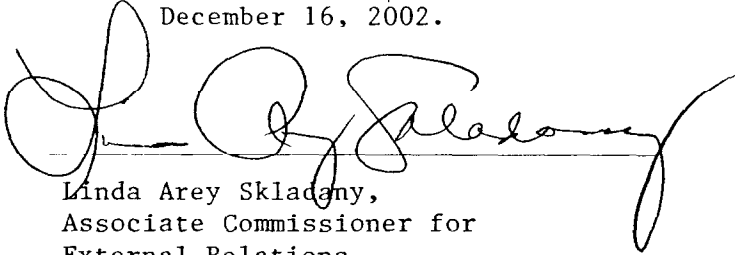
Persons attending FDA’s advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Jayne E. Peterson at least 7 days in advance of the meeting.



Notice of this meeting is given under the Federal Advisory Committee Act
(5 U.S.C. app. 2).

Dated: Dec 16, 2002
December 16, 2002.

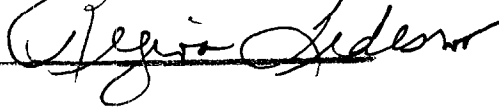
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Linda Arey Skladany,
Associate Commissioner for
External Relations.

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

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**CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL**

A handwritten signature in black ink, appearing to read "Regina Sedeno", written over a horizontal line.